

K106578

9.0 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT Asahi Intecc Co., Ltd.
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**OFFICIAL
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SEP 22 2010

TRADE NAME: ASAHI SION PTCA Guide Wire

COMMON NAME: Guide Wire

**CLASSIFICATION
NAME:** Wire, Guide, Catheter

**DEVICE
CLASSIFICATION:** Class 2 per 21 CFR §870.1330

PRODUCT CODE DQX

PREDICATE DEVICE: Asahi – SUOH PTCA Guide Wire – 510(k) K083904
Asahi – Asahi PTCA Guide Wire – 510(k) K070945
Asahi – JoWire Neo's PTCA Guide Wire – 510(k) K022762

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ASAHI SION PTCA Guide Wire is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 180 cm and 300 cm lengths. The extension wire is connected to the end of the guide wire outside the body. The guide wire is constructed from a stainless steel core wire with platinum-nickel and stainless steel coils. The coil assembly consists of an inner coil and an outer coil, and there is a safety wire for which is soldered to the inner and outer coils and the core wire. The distal end of the guide wire has a radiopaque tip to achieve visibility, and is available in a straight configuration and can be made to bend easily with the vessel curve. A hydrophilic coating is applied to the distal portion of the guide wire. The proximal section of the guide wire is coated with PTFE.

INDICATION FOR USE:

The ASAHI SION PTCA Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi SION PTCA Guide Wire is not to be used in the cerebral blood vessel.

TECHNICAL CHARACTERISTICS:

Comparisons of the ASAHI SION PTCA Guide Wire and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

The ASAHI SION PTCA Guide Wire is similar in design - device dimensional specifications and manufacturing process, and intended use, operating principle, shelf life and sterilization process are the same and materials that have been used in other predicate devices in that its core wire, tip coils and solders remain the same.

PERFORMANCE DATA:

All components that come in direct contact with the patient have a long history of use in medical devices and are proven to be biocompatible for use in the vasculature. Furthermore, this submission contains reference to a predicate ASAHI device that uses the same materials as used in the subject device. In vitro bench testing, including tensile strength, torque strength, torqueability, tip flexibility, coating adherence, catheter compatibility and integrity (particulate testing) etc were conducted on the ASAHI SION PTCA Guide Wire. This 510(k) notice includes mechanical and functional bench testing that demonstrates that the ASAHI SION PTCA Guide Wire performs as intended.

SUMMARY/CONCLUSION:

The ASAHI SION PTCA Guide Wire characteristics are substantially equivalent to the specified predicate devices and other currently marketed devices for the same indication for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Asahi Intecc Co. Ltd.
c/o Mr. Yoshi Terai
President, CEO
Asahi Intecc USA, Inc.
2500 Red Hill Avenue, Suite 210
Santa Ana, CA 92705

SEP 22 2010

Re: K100578
Trade/Device Name: ASAHI SION PTCA Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: September 17, 2010
Received: September 20, 2010

Dear Mr. Terai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

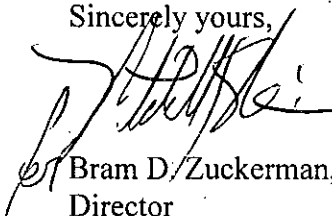
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

2.

INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K100578

K100578

Device Name: ASAHI SION PTCA Guide Wire

SEP 22 2010

Indications for Use:

The ASAHI SION PTCA Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI SION PTCA Guide Wire is not to be used in the cerebral blood vessel.

Prescription Use X

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDER, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K100578

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